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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,713	11/27/2000	Genichiro Soma	101149-00008	7273

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[REDACTED] EXAMINER

SHAHNAN SHAH, KHATOL S

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1645

DATE MAILED: 12/04/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

File copy

Office Action Summary	Application No.	Applicant(s)	
	09/700,713	SOMA ET AL.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 December 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) 3,13 and 14 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4-6,9-12,15 and 16 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>12</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' amendment B, received December 06, 2001, paper #8 is acknowledged. Claims 3, 5, 6 and 15 were amended. Claims 7-8 were canceled. Substitute specification was entered. The title of the invention was amended. Amended claim 3 now recites a method for preparing a feedstuff not a method of use and is withdrawn from consideration as being drawn to non-elected invention.
2. Currently claims 1-6 and 9-16 are pending. Claims 3 and 13-14 are withdrawn from consideration as being drawn to non-elected invention.
3. Claims 1-2, 4-6, 9-12 and 15-16 are under consideration.

Information Disclosure Statement

4. The information disclosure statement filed 11/27/2000 and supplementary Information Disclosure Statement, received December 06, 2001 paper 12 are acknowledged and have been considered by the examiner. (see attached PTO forms 1449).

Prior Citations of Title 35 Sections

5. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Priority

6. Objection to priority status made in paragraphs 6 and 7 of the office action mailed June 01, 2001 is maintained. It is noted, however, that applicants have not filed a translated copy of the priority application 84399 filed in Japan on 3/26/1999. Complete priority statement still is missing from specification. In pages 3 and 4 of the response filed December 06, 2001, applicants mention of an amendment of the specification to include priority statement. The newly amended specification does not recite such a statement.

Objections Withdrawn

7. Objection to the title made in paragraph 5 of the office action mailed June 01,2001 is withdrawn in view of applicants' amendments.
8. Objection to the specification made in paragraph 8 of the office action mailed June 01,2001 is withdrawn in view of applicants' amendments.

Rejections Withdrawn

9. Rejection of claims 3 and 7 under 35 USC 101, made in paragraph 9 of the office action mailed June 01,2001 is withdrawn in view of applicants' amendments.
10. Rejection of claims 1-12 and 15-16 under 35 USC 112 first paragraph, made in paragraph 10 of the office action mailed June 01,2001 is withdrawn in view of applicants' amendments.
11. Rejection of claims 1-12 and 15-16 under 35 USC 112 second paragraph, made in paragraph 11 of the office action mailed June 01,2001 is withdrawn in view of applicants' amendments.
12. Rejection of claims 1-12 and 16 under 35 USC 102 (b), made in paragraph 12 of the office action mailed June 01,2001 is withdrawn in view of applicants' amendments.
13. Rejections of claims 1-12 and 15-16 under 35 USC 103, made in paragraphs 13 and 14 of the office action mailed June 01,2001 is withdrawn in view of applicants' amendments.

New Grounds for Rejection

Claim Rejections - 35 USC § 112

14. Claims 6, 12, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6, recites the phrase “ an admixture of an immunity-activating or infection-preventing amount”. It is not clear what applicants intend in recitation of said phrase.

Claim 12 recites the limitation "the perish of claim 5". There is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites a Markush group “ wherein the infection is caused by an infectious microbe selected from the group consisting of” and then list groups of diseases not microbes. This is not a proper Markush format and thus unclear.

Claim Rejections - 35 USC § 102

15. Claims 1, 2, 4, 5, 6, 9, and 10-12 are rejected under U.S.C. 102(b) as being anticipated by Soma et al. (US Patent No. 5,346,891). Prior art of record.

Claims are drawn to a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 2000 as measured by SDS-PAGE method. The product is a low molecular weight lipopolysaccharide and capable of activating immunity or prevent infection.

Applicant's arguments filed 12/06/2002 have been fully considered but they are not persuasive.

Applicants argue, “Soma does not explicitly or implicitly teach adding these lipopolysaccharides to feed, and then subsequently feeding this fortified feed to fish or crustacea.”

It is the examiner's position that the rejected claims are drawn to a product and the same product is taught by Soma et al. However, intended use does not impart any critical impact or weight on the physical preparation and the patentability of the product.

Soma et al. disclose a product prepared from gram negative bacteria, that has a molecular

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weight of 5000 ± 1000 as measured by SDS-PAGE method. The product is a low molecular weight lipopolysaccharide and capable of activating immunity (see abstract).

Soma et al. disclose three products (novel lipopolysaccharides) from gram negative bacteria that have molecular weights of $5,000 \pm 1000$ and $6,500 \pm 2,500$ as measured by SDS-PAGE method. (see abstract and claims). The products has been used as immunity stimulators via oral administration for different animals. (see column 18 lines, 25-60 and claims 4-6). Soma et al. teach a 96% pure LPS with the dominant molecular weight of 5000 ± 1000 as measured by SDS-PAGE (see columns 3-4). One of the lipopolysaccharide is produced by a strain of the species *Pantoea agglomerans* (see column 8 line 65 and claim 3). Soma et al. teach an agent for activating immunity comprising the lipopolysaccharide and pharmaceutically or veterinarianily acceptable carrier (see claims 4-6).

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

16. Claims 1, 2, 5, 6, 9, and 11-12 are rejected under U.S.C. 102(b) as being anticipated by Mizuno et al. (WO96/23002) Abstract and Summary in English Attached.

Claims are drawn to a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 2000 as measured by SDS-PAGE method. The product is a low molecular weight lipopolysaccharide and capable of activating immunity or prevent infection. The product

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is intended to be used as a feedstuff additive for crustaceans and fish.

However, intended use does not impart any critical impact or weight on the physical preparation and the patentability of the product.

Mizuno et al. teach a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 1000 as measured by SDS-PAGE method. The product is a low molecular weight lipopolysaccharide being substantially free from other molecular weights and capable of activating immunity and preventing infection (see abstract). Mizuno et al. teach low molecular weight lipopolysaccharide from *Pantoea* species.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

17. Claims 1, 2, 5, 6, and 9-12 are rejected under U.S.C. 102(b) as being anticipated by Soma et al. (US Patent No. 5,494,819). Prior art of record.

Claims are drawn to a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 2000 as measured by SDS-PAGE method. The product is a low molecular weight lipopolysaccharide and capable of activating immunity or prevent infection. The product is intended to be used as a feedstuff additive for crustaceans and fish.

However, intended use does not impart any critical impact or weight on the physical preparation and the patentability of the product.

Soma et al. (US Patent No. 5,494,819) teach a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 1000 as measured by SDS-PAGE method (see column 3). The product is a low molecular weight lipopolysaccharide and capable of activating immunity (see column 5). The product can be used as feed or feed additives for veterinary use. (see column 5).

Soma et al. disclose three products (novel lipopolysaccharides) from gram negative bacteria that have molecular weights of $5,000 \pm 1000$ and $6,500 \pm 2,500$ as measured by SDS-PAGE method. (see columns 3, 10, abstract and claim 1). The products can be used as immunity stimulators with acceptable carriers (see column 5 and column 17). Soma et al. teach a 96% pure LPS with the dominant molecular weight of 5000 ± 1000 as measured by SDS-PAGE (see columns 3). One of the lipopolysaccharide is produced by a strain of the species *Pantoea agglomerans* (see abstract and claim 1).

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Rejections - 35 USC § 103

18. Claims 1-12 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soma et al. (US Patent No. 5,494,819) in view of Takahashi et al. (US Patent No. 5,641,761) Prior art of record.

Claims are drawn to a product prepared from gram-negative bacteria, that has a molecular weight of 5000 ± 2000 as measured by SDS-PAGE method. The product is a low molecular weight lipopolysaccharide and capable of activating immunity or prevent infection. The product is intended to be used as a feedstuff additive for crustaceans and fish.

Soma et al. teach a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 1000 as measured by SDS-PAGE method (see column 3). The product is a low molecular weight lipopolysaccharide and capable of activating immunity (see column 5). The product can be used as feed or feed additives for veterinary use. (see column 5).

Soma et al. disclose three products (novel lipopolysaccharides) from gram negative bacteria that have molecular weights of $5,000 \pm 1000$ and $6,500 \pm 2,500$ as measured by SDS-PAGE method. (see columns 3, 10, abstract and claim 1). The products can be used as immunity stimulators with acceptable carriers (see column 5 and column 17). Soma et al. teach a 96% pure LPS with the dominant molecular weight of 5000 ± 1000 as measured by SDS-PAGE (see columns 3). One of the lipopolysaccharide is produced by a strain of the species *Pantoea agglomerans* (see abstract and claim 1). Soma et al. do not explicitly teach use of feedstuff additive against infectious diseases for crustaceans and fish. However, Takahashi et al. teach a preventive agent (feedstuff) against infectious diseases of crustaceans comprising of a polysaccharide (glucan) from fungi. (see title and abstract). Takahashi et al. tested their product on Kuruma prawns (see examples 1-7). Takahashi et al. teach a method of enhancing the immune system of crustaceans by feeding them a water-soluble form of their product (see claim 1). Takahashi et al. also teach a method of treating crustaceans' infections such as vibrio infections, mycotic infections, and viral infections by feeding them their product.

It would have been *prima facie* obvious to a person skilled in the art at the time the invention was made to replace the products taught by Takahashi et al. with the product taught by Soma et al. to obtain the disclosed invention. One having ordinary skill in the art would have been motivated to replace the high molecular weight molecules of Takahashi et al. and with the low molecular weight lipopolysaccharide of Soma et al. which has excellent immuno-stimulating activity and may be provided at low cost and a large amount (see Soma et al., column 2, line 50-55).

19. Claim 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi et al. (US Patent No. 5,641,761) in view of Soma et al. (US Patent No. 5,494,819). Prior art of record.

Claim 4 is drawn to a method of activating immunity or preventing infection in crustaceans or fish comprising administering an effective amount of low molecular weight lipopolysaccharide to crustaceans or fish.

Takahashi et al. teach a method of activating immunity or preventing infection in crustaceans comprising administering or feeding a polysaccharide to crustaceans (see claims). Takahashi et al teach a method of enhancing the immune system of crustaceans (Kuruma prawns, see examples 1-7). Takahashi et al teach a method of treating crustaceans' infections such as vibrio infections, mycotic infections, and viral infections. Takahashi et al. do not teach low molecular weight lipopolysaccharide. However Soma et al. teach a product prepared from gram negative bacteria, that has a molecular weight of 5000 ± 1000 as measured by SDS-PAGE method (see column 3). The product is a low molecular weight lipopolysaccharide and capable of activating immunity (see column 5). The product can be used as feed or feed additives for veterinary use. (see column 5).

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It would have been *prima facie* obvious to a person skilled in the art at the time the invention was made to modify the method taught by Takahashi et al. by using the product taught by Soma et al. to obtain the disclosed invention. One having ordinary skill in the art would have been motivated to replace the high molecular weight molecules of Takahashi et al. and with the low molecular weight lipopolysaccharide of Soma et al. which has excellent immuno-stimulating activity and may be provided at low cost and a large amount (see Soma et al., column 2, line 50-55).

Conclusion

20. No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7: 30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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11/21/2002


MARK NAVARRO
PRIMARY EXAMINER